UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/479,038	06/07/95	DROHAN	W 1327.0440006

18M1/0107

STERNE KESSLER GOLDSTEIN AND FOX
1100 NEW YORK AVENUE N W
SUITE 600
WASHINGTON DC 20005-3934

EXAMINER	
ZEMAN, M	
ART UNIT	PAPER NUMBER
1815	11

DATE MAILED: 01/07/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 1/4/96.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, ıichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause ə application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 136(a).

sposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) 1-11 + 21-23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 12-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

ıplication Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

iority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

tachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6+8

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

BEST AVAILABLE COPY

DETAILED ACTION

1. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1815.

2. Applicant's election of Group II, claims 12-20 in paper number 10, dated 11/4/96, is acknowledged. The election was made without traverse. Accordingly, claims 1-11 are withdrawn from consideration.

3. All of the art listed in the information disclosure statements (papers 6 and 8) has been carefully considered.

Specification

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to set forth the invention in such full, clear, concise and exact terms such that one of ordinary skill in the art could make or use the invention.

The invention claimed in pending claims 12-20 is a delivery system for the delivery of antibodies to a patient in a fibrin sealant matrix. The specification filed 6/7/95 details how to

BEST AVAILABLE COPY

include antibiotics, chemotherapeutics and growth factors in the fibrin sealant, however there is no discussion of the inclusion of antibodies. In view of this, this application is accorded the filing date of the instant application, 6/7/95. Priority to earlier parent applications is denied.

In the field of therapeutic antibodies, certain problems must be addressed. First, for the particular condition, wound, disease or cancer, appropriate antibodies must be selected that are problem-specific. These antibodies need to exhibit activity against their target in *in vitro* studies. Ideally, the chosen antibodies would induce limited immunoreactivity in the patient. Second, the binding kinetics of the antibody must be determined both in *in vitro* and animal model studies so that an approximate effective dosage can be calculated. Third, the best administrative method must be determined. The three most basic methods, i.v., i.p. and topical, have different advantages and disadvantages, depending on the problem, and desired outcome. For example, for antibodies delivered intravenously for the treatment of cancer, the antibody must be distributed throughout the tumor vascularization, be transported across the microvascular wall, and through interstitial space to reach its target in the tumor. Once the compound has been delivered, the ability of the antibody to reach and react with its target must be determined. If the antibody is delivered in an implant, the release kinetics and resulting activity are crucial pieces of information. If the implant is a fibrin matrix clot, the biochemistry of the inclusion of an antibody, its release from the fibrin matrix and its activity upon release need to be addressed.

There is no exact teaching in the art of the inclusion of specific antibodies into a fibrin matrix for use as a treatment, or passive immunization. When the teachings in the prior art are

BEST AVAILABLE COPY

inadequate, the level of disclosure in a specification must be greater. The specification as filed does not address the problems listed above. No particular antibodies are discussed, nor are there demonstration of specific antibody activity. No binding kinetics or appropriate administration routes are disclosed. No antibody-release and activity information is discussed, nor are the biochemical and kinetic consequences of containment of an antibody within a fibrin clot identified. The pending claims require "sustained release" of the antibody, yet there is no demonstration that antibodies are released from the matrix, the kinetics of any release, nor any timetable of half-lives of antibiotics in this type of matrix. Also required are solid forms of the antibody, but there is no discussion of preferred solidification methods. No explanation of an emulsified antibody is given. An emulsion of a large protein could behave in a different manner than antibodies solubilized in water.

Claim Rejections - 35 USC § 112

5. Claims 12-20 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the objection to the specification.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

BEST AVAILABLE COPY

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800

mkz
January 6, 1997

BEST AVAILABLE COPY